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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,206	11/25/2003	William Hallen Falls JR.	MR1035-1346	4075

4586 7590 02/08/2007

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EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	PAPER NUMBER
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,206	FALLS ET AL.	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-48 and 51-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-48 and 51-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed on November 9, 2006. Examiner acknowledges claims 38-48 and 51-55 are pending in this application, with claims 38, 45, and 52 having been amended and claims 1-37, 49-50, 56 and 57 having been cancelled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 38-48 and 51-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP §608.04.

Specifically, independent claims 38, 45, and 52 now recite the claim limitation "a synthetic or cotton yarn sewing thread..."; however, the originally filed disclosure dose not provide evidence that Applicant possessed the newly claimed invention at the time the application was a filed. In fact, the original specification of the instant invention discloses, "the thread used for stitching the hem is for example, a synthetic thread." (Page 5, Line 19). There is no support in the original disclosure as filed for the thread to

be a yarn nor for the thread to be made of cotton; and therefore, the subject matter added to the independent claims 38, 45, and 52 is considered new matter and must be cancelled from the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 38, 39, 42-46, and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall (US 4205680 A) in view of McAvinn (US 4244369 A).

As to Claim 38, Marshall discloses a surgical towel (10) comprising a sheet of woven fabric comprising at least one stitched hem (Figures 1 and 2), a thread for stitching the hem (22), and at least one piece of x-ray detectable material (21) attached to the fabric by the tread, the x-ray material protruding from the hem (Figures 1 and 2) allowing visual identification of the x-ray material's location, the x-ray detectable material comprising identifying characteristics to identify an x-rayed object as a surgical towel (Column 1). Yet, Marshall does not expressly disclose the limitation of the thread to be of a different color than the fabric for stitching the hem and the thread color to be visually identifying the surgical towel as x-ray detectable. However, at the time the invention was made it was well known for thread to be a different color than the fabric. Specifically, McAvinn teaches the use of a thread (22) that is highly reflective and

contrasts with the color of blood for the purpose of increasing the visibility of the absorbent material in the presence of blood. (Column 2). Further, McAvinn discloses the composition of the thread to have a central layer (24) made of a metallic reflective material sandwiched between two transparent outer layers (26), which enable the metallic central layer to be seen. (Figure 3). Naturally the reflective nature of the thread will distinguish from the color of the fabric regardless of saturation by blood or water, and regardless of the color in which the towel has been dyed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the article of Marshall to include a thread color different from the fabric to increase the visibility of the absorbent article whether inside or outside the body, as taught by McAvinn.

As to Claim 45, Marshall discloses a surgical towel (10) comprising a sheet of woven fabric comprising at least one stitched hem (Figures 1 and 2), a thread for stitching the hem (22), and at least one piece of x-ray detectable material (21) attached to the fabric by the tread, the x-ray material protruding from the hem (Figures 1 and 2) allowing visual identification of the x-ray material's location, the x-ray detectable material comprising identifying characteristics to identify an x-rayed object as a surgical towel (Column 1). Yet, Marshall does not expressly disclose neither the ply ratio of the sheet of woven cotton fabric nor the limitation of the thread to be of a different color than the fabric for stitching the hem and the thread color to be visually identifying the surgical towel as x-ray detectable. However, at the time the invention was made the ply ratio and thread of different color than fabric was well known. Regarding the ply ratio, it is

well known that the medical personnel would choose a ply-ratio commensurate with the surgical procedure being preformed. For example the absorptive quality required for a nosebleed is substantially less than the absorptive quality requirement for an open-heart surgery procedure. Moreover, Applicant has not asserted that the specific ply ratio recited provides a particular advantage, solves a stated problem, or serves a purpose different from that of providing a pliable absorptive material for insertion into the body during a surgical procedure, thus the use of a single-ply towel lacks criticality in its design. Furthermore, one of ordinary skill in the art would choose a ply-ratio commensurate with the surgical procedure being preformed. Regarding the thread color, McAvinn teaches the use of a thread (22) that is highly reflective and contrasts with the color of blood for the purpose of increasing the visibility of the absorbent material in the presence of blood. (Column 2). Further McAvinn discloses the composition of the thread to have a central layer (24) made of a metallic reflective material sandwiched between two transparent outer layers (26), which enable the metallic central layer to be seen. (Figure 3). Naturally the reflective nature of the thread will distinguish from the color of the fabric regardless of saturation by blood or water, and regardless of the color in which the towel has been dyed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the article of Marshall to include a thread color different from the fabric to increase the visibility of the absorbent article whether inside or outside the body.

As to Claim 42, the system of Marshall as modified by McAvinn is discussed in **Claim 38,** yet the limitation of the woven fabric to be made of cotton, synthetic material

or a combination thereof has yet to be discussed. However, at the time the invention was made the use of cotton, synthetic material or a combination thereof was well known. Specifically, McAvinn uses cotton because of its absorptive quality and open mesh structure. (Column 2, Lines 30-35). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Marshall as modified by McAvinn to include woven cotton because of its absorptive nature.

As to Claim 43, the system of Marshall as modified by McAvinn is discussed in **Claim 38,** yet does not expressly disclose the single-ply characteristics of the sheet. However, at the time the invention was made ply-ratios were well known. Specifically, it is well known that the medical personnel would choose a ply-ratio commensurate with the surgical procedure being preformed. For example the absorptive quality required for a nosebleed is substantially less than the absorptive quality requirement for an open-heart surgery procedure. Therefore it would have been obvious to one having ordinary skill in the art to modify the system of Marshall as modified by McAvinn to have a ply ratio capable of assisting medical personnel in the effective containment of fluid in medical procedures.

As to Claims 44 and 51, the system of Marshall as modified by McAvinn is discussed in **Claims 38 and 45,** respectively, yet the limitations of the physical characteristics of the x-ray detectable material to be a flexible strip through which the hem stitching is sewn have yet to be discussed. However, at the time the invention was made the recited physical characteristics of the x-ray detectable material were known.

Specifically, McAvinn teaches the "filament (20) may be made of a thermoplastic polymeric material containing a radiopaque material such as barium sulfate. (Column 2, Lines 43-46). Naturally, the composition of the filament and the placement of the filament into the woven cloth would allow for some flexibility in the strip. Further, depending on the placement of the strip, the strip may be sewn in place to maintain the location of the radioactive element. Finally, McAvinn's flexible strip serves a purpose of providing a means for smooth incorporation into the sheet (12). (Figure 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Marshall to incorporate the flexible strip of McAvinn for the purpose of maintaining the pliable nature of the fabric while providing x-ray detectable material.

As to Claims 39 and 46, the system of Marshall as modified by McAvinn is discussed in **Claims 38 and 45,** respectively, yet the limitations of the x-ray material being made of Barite, Barium, or $BaSO_4$. However, at the time the invention was made, the use of Barium sulfate ($BaSO_4$) for x-ray detection was well known. Specifically, McAvinn teaches the "filament (20) may be made of a thermoplastic polymeric material containing a radiopaque material such as barium sulfate." (Column 2, Lines 43-46). Barium Sulfate is a well-known material that is used in x-ray detection because of its ability to be safely introduced into the body. Therefore it would have been obvious to one having ordinary skill in the art to modify the system of Marshall as modified by McAvinn for the purpose maintaining patient safety while providing a means for x-ray detection.

6. **Claims 40, 41, 47, and 48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall (US 4205680 A) in view of McAvinn (US 4244369 A), and further in view of Debusk (US 5792128 A).

As to Claims 40 and 47, the system of Marshall as modified by McAvinn is discussed in **Claims 38 and 45,** respectively, yet does not expressly disclose the x-ray detectable material comprising polyvinyl chloride (PVC). However, the use of the recited x-ray detectable materials was known at the time the invention was made. Specifically, Debusk teaches an x-ray detectable material comprising 60% $BaSO_4$ and 40% PVC (see "polyvinyl chloride filled with at least about 60%...barium sulfate" in lines 30-32 of Column 4) for the purpose of a safe radioactive material capable of being used within the body for x-ray detection. Finally, the recited x-ray detection materials are well-known materials that are used in x-ray detection because of its ability to be safely introduced into the body. Therefore it would have been obvious to one having ordinary skill in the art to modify the system of Marshall as modified by McAvinn for the purpose maintaining patient safety while providing a means for x-ray detection.

As to Claims 41 and 48, the system of Marshall as modified by McAvinn is discussed in **Claims 38 and 45,** respectively, yet does not expressly disclose the x-ray detectable material having 60% $BaSO_4$ and 40% PVC. However, the use of the recited x-ray detectable materials was known at the time the invention was made. Specifically, Debusk teaches an x-ray detectable material comprising 60% $BaSO_4$ and 40% PVC (see "polyvinyl chloride filled with at least about 60%...barium sulfate" in lines 30-32 of

Column 4) for the purpose of a safe radioactive material capable of being used within the body for x-ray detection. Finally, the recited x-ray detection materials are well-known materials that are used in x-ray detection because of its ability to be safely introduced into the body. Therefore it would have been obvious to one having ordinary skill in the art to modify the system of Marshall as modified by McAvinn for the purpose maintaining patient safety while providing a means for x-ray detection.

7. **Claims 52 and 53** are rejected under 35 U.S.C. 103(a) as being unpatentable over McAvinn (US 4244369 A).

As to Claim 52, McAvinn discloses a surgical towel (absorbent article) comprising, a sheet of woven cotton fabric (12) having four (4) edges (Figures 1, 6, and 7), at least one hem stitched in at least one of the four edges (Figure 6), a thread of a different color (22) than a color of the cotton fabric for stitching the at least one hem, the color of the thread visually identifying the surgical towel as x-ray detectable; and at least one piece of x-ray detectable material (20) through which the hem stitching is sewn, the x-ray detectable material protruding from the hem but not extending past the edge of the fabric, allowing visual identification of the x-ray detectable material's location, the x-ray detectable material comprising identifying characteristics to identify an x-rayed object as a surgical towel. Regarding the surgical towel limitation, McAvinn discloses an invention related to "absorbent articles and more particularly to surgical sponges. Because McAvinn's invention is in a surgical environment absorbent articles broadly includes towels. Regarding the placement of the x-ray detectable material, McAvinn

discloses the x-ray detectable material (20) located with in the sheet (12). As well known in the art, the stitching of the x-ray detectable material through the hem would contain the movement of the x-ray detectable material with in the sheet (12). Further, the stitching pattern disclosed in Figure 6 contains vertical hem lines parallel to edges (18a and 18b), the placement of the x-ray detectable material inside the these hemlines enables the placement of the x-ray detectable material to not extend past the edge of the fabric. Yet, McAvinn does not teach the single-ply ratio of the sheet. However, at the time the invention was made the ply ratio and thus absorptive quality of a towel would be modified by the medical personnel depending on the procedure being performed. For example the absorptive quality required for a nosebleed is substantially less than the absorptive quality requirement for an open-heart surgery procedure. Moreover, Applicant has not asserted that the specific ply ratio recited provides a particular advantage, solves a stated problem, or serves a purpose different from that of providing a pliable absorptive material for insertion into the body during a surgical procedure, thus the use of a single-ply towel lacks criticality in its design. Furthermore, one of ordinary skill in the art would choose a ply-ratio commensurate with the surgical procedure being preformed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the article of McAvinn to effectively control and identify the absorptive needs of the patient.

As to Claim 53, McAvinn is discussed in **Claim 52**, yet the limitations of the x-ray material being made of Barite, Barium, or $BaSO_4$ have yet to be discussed. However, at the time the invention was made, the use of Barium sulfate ($BaSO_4$) for x-

ray detection was well known. Specifically, McAvinn teaches the "filament (20) may be made of a thermoplastic polymeric material containing a radiopaque material such as barium sulfate." (Column 2, Lines 43-46). Barium Sulfate is a well-known material that is used in x-ray detection because of its ability to be safely introduced into the body. Therefore it would have been obvious to one having ordinary skill in the art to modify the system of Marshall as modified by McAvinn for the purpose maintaining patient safety while providing a means for x-ray detection.

8. **Claims 54-55** are rejected under 35 U.S.C. 103(a) as being unpatentable over McAvinn (US 4244369 A) in view of Debusk (US 5792128 A).

As to Claim 54, McAvinn is discussed in **Claim 52**, yet does not expressly disclose the x-ray detectable material comprising polyvinyl chloride (PVC). However, the use of the recited x-ray detectable materials were known at the time the invention was made. Specifically, Debusk teaches an x-ray detectable material comprising 60% $BaSO_4$ and 40% PVC (see "polyvinyl chloride filled with at least about 60%...barium sulfate" in lines 30-32 of Column 4) for the purpose of a safe radioactive material capable of being used within the body for x-ray detection. Finally, the recited x-ray detection materials are well-known materials that are used in x-ray detection because of its ability to be safely introduced into the body. Therefore it would have been obvious to one having ordinary skill in the art to modify the system of Marshall as modified by McAvinn for the purpose maintaining patient safety while providing a means for x-ray detection.

As to Claim 55, McAvinn is discussed in **Claims 52,** yet does not expressly disclose the x-ray detectable material having 60% $BaSO_4$ and 40% PVC. However, the use of the recited x-ray detectable materials were known at the time the invention was made. Specifically, Debusk teaches an x-ray detectable material comprising 60% $BaSO_4$ and 40% PVC (see "polyvinyl chloride filled with at least about 60%...barium sulfate" in lines 30-32 of Column 4) for the purpose of a safe radioactive material capable of being used within the body for x-ray detection. Finally, the recited x-ray detection materials are well-known materials that are used in x-ray detection because of its ability to be safely introduced into the body. Therefore it would have been obvious to one having ordinary skill in the art to modify the system of Marshall as modified by McAvinn for the purpose maintaining patient safety while providing a means for x-ray detection.

Response to Arguments

9. Applicant's arguments filed November 9, 2006 have been fully considered but they are not persuasive. Applicant has amended independent claims 38, 45 and 52 in an attempt to overcome the prior art made of record to recite the new limitations of "a synthetic or cotton yarn sewing thread...". However, there is no support within the specification for the aforementioned independent claims. Specifically, in Applicant's specification (Page 5, Line 19), Applicant discloses, "the thread used for stitching the hem is for example, a synthetic thread." There is no recitation of the thread to be made of yarn nor is there a recitation of the thread to be made of a cotton fiber. Regarding

Applicants arguments as to the prior art teaching of McAvinn's thread. Applicant is directed to Column 2, Lines 46-58, wherein McAvinn teaches a thread having outer layers made of a transparent plastic and an inner core made of a metallic material. In Applicant's arguments, Applicant asserts that the metallic core does not enable the thread to be synthetic. However, as well known in the art, many plastics and metals are formed by a synthetic process. Thus, the very nature of the McAvinn thread reference having a metallic core does not discredit the nature of the thread being formed of a synthetic material. Furthermore, the fact that the outer layer is made from plastic, a synthetic material, means that the thread has a synthetic component, thereby enabling the thread to be described as a synthetic. Finally, in regards to Applicant's amendment to include specifics of the identifying characteristics. Intrinsically the shape of the radioactive filament in a rectangular shape as shown in Figure 1 of McAvinn serves to provide identifying characteristics to the surgical towel. Furthermore, extrinsic evidence is provided by the Fabian reference 2005/0049563 which teaches the use of other shapes such as stars circles and boxes (Figures 5-10) to provide additional identifying characteristics to the surgical towel. Consequently, though Applicant's arguments have been fully considered by the Examiner, these arguments have been deemed not persuasive. Therefore, the rejection of claims 38-48 and 51-55 has been maintained.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The balance of art listed by US patent number below, shows

additional inventions in the field of articles capable of being used as surgical towels in detection environments.

Dyer; John et al.	US 5045080
Fabian, Carl E.	US 20050049563
Papp, Jr.; Stephen	US 4935019
Shen; Albert	US 4626251
Taylor; Jeffrey L.	US 4626311

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771
January 30, 2007

JUSTINE R. YU
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2/1/07